K011537
p1/4

JAN 0 7 2002

# 510(K) SUMMARY

The 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR, Section 807.87

**Submitted by**

Yaw C. Yang, Ph.D.
DYNAMIC TECHNOLOGY CORP.
2F, 53, Park Ave. II, Science-Based Industrial Park.
Hsinchu, Taiwan, R.O.C.
Tel.: 886-3-578-9566
Fax: 886-3-579-9541

**Contact**

Yaw C. Yang, Ph.D.
DYNAMIC TECHNOLOGY CORP.
2F, 53, Park Ave. II, Science-Based Industrial Park.
Hsinchu, Taiwan, R.O.C.
Tel.: 886-3-578-9566
Fax: 886-3-579-9541

**Date prepared:** May./15/2001

**Classification:** Class III, per 876.5860 of 21 CFR

**Device Name :**

**Trade Name:** DYNAMIC Hollow Fiber Dialyzer DS-Series,
Model: POLYSULFONE 100 HFS, POLYSULFONE 130 HFS

**Classification Name:** High permeability dialyzer

**Predicate device :**

Fresenius Hemoflow F-Series High-Flux Dialyzer (K870724)
Minntech Primus Hollow fiber Dialyzer (K923727)
DYNAMIC Hollow Fiber Dialyzer DS-Series,
Model: DS-190 (K982134)

**Device Classifications:** A hemodilysis system has been viewed by the Gastroenterology-Urology device classification panel.

**Performance Standard:** No performance standard or special controls have been established by the Food and Drug Administration for dialyzer.

## Device Description

The DYNAMIC Hollow Fiber Dialyzer DS-Series is disposable artificial kidneys designed for use in hemodialysis. These dialyzers are membrane-type devices consisted of Polysulfone hollow fibers contained within a transparent plastic case. Polysulfone has an efficient fiber construction which has high-flux and outstanding biocompatible membrane for hemodialysis. Each hollow fiber has an inner diameter of approximately 200 microns and wall thickness of 40 microns.

The medical device is potted by a biocompatible polyurethane placed at both ends of a case. This action is provided to secures the fibers and serves as a moisture barrier. A biocompatible silicon "O-ring" provides a seal between the case and end-caps. Dialysate system in which the dialysate flows to waste after one single passage through the hemodialyzer. Removal of metabolism toxins and waste products is taken away from the patients' blood into the counter-current flowing dialysate. The dialysate exits the devices via a dialysate outlet port.

DYNAMIC Hollow Fiber Dialyzer DS-Series consists of POLYSULFONE 100 HFS(DS-100), POLYSULFONE 130 HFS(DS-130) and DS-190. The effective surface area of the models are 1.0$m^2$, 1.3$m^2$ and 1.9$m^2$ respectively, provides efficient solute clearance and high ultrafiltration rate. Well balanced diffusion and ultrafiltration provide dialysis efficiency and stability that enable short-term dialysis.

The proposed dialyzers are substantial equivalent to DS-190(K982134) and predicate device including Fresenius Hemoflow F-Series High-Flux Dialyzer (K870724) and Minntech Primus Hollow fiber Dialyzer (K923727), with the same Polysulfone fiber.

The device will be packed in a standard medical grade pouch comprised designed paper, thermoplastic film, and then put in a carton.

These hemodialyzers sterilized with ethylene oxide are sterile and non-pyrogenic.

Biocompatibility tests were performed acute intracutaneous reactivity study in the rabbit, hemolysis study, cytotoxicity study, acute systemic toxicity study in the mouse, USP rabbit pyrogen. These test results indicated these dialyzers passed all tests listed above, Therefore, Dynamic DS-Series dialyzers are identified freedom from biological hazard.

## Indications for use

The DYNAMIC Hollow Fiber Dialyzer DS-Series are indicated for use whenever a patient is in acute or chronic renal failure and hemodialysis is prescribed by a physician. Therefore, use of this device should be only on the direction of a physician who has evaluated all of the aspects of the patient's illness.

The indications for use of DYNAMIC Hollow Dialyzer DS-Series will be the almostly same as those of the predicate dialyzers

## Substantial Equivalence Statement:

In the opinion of the DYNAMIC Hollow Fiber Dialyzer DS-Series, model: POLYSULFONE 100 HFS and POLYSULFONE 130 HFS are substantially equivalent to the certain medical devices that were current in commercial distribution in the United states. This opinion is based on the following facts and conclusions:

A. In the design intent, material, and construction employed to accomplish the same intended use.

The list of materials from which no various components are made. There is a brief explanation of the testing procedures used to qualify the dialyzer materials and the dialyzer itself in terms of biocompatibility, toxicity, pyrogen, performance and sterility.

B. The operation principles of this device is almost the same as those of predicate dialyzers. In Vitro testing was performed on the proposed dialyzers to determine the following: Urea, Creatinine, Phosphate, Vitamin B12 clearance at varying blood flows, Ultrafiltration coefficient at varying transmembrane pressure, Blood priming volumes, Residual blood volume, Pressure drops and Sieving coefficients, The results of

these tests confirmed that the proposed dialyzers are substantially equivalent to the predicate dialyzers.

## Conclusions

Compared to the predicate dialyzers, there are no new design intent, intended use, operational principle and technologies. The construction materials have the same biocompatible characteristics. *In vitro* test results have been presented to verify comparable performance to predicate devices. The proposed dialyzers are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use.

Dynamic Technology Corp. concluded that the models identified as POLYSULFONE 100 HFS (DS-100) and POLYSULFONE 130 HFS (DS-130) are substantially equivalent to the predicate dialyzers including Fresenius Hemoflow F-Series High-Flux Dialyzer(K870724) and Minntech Primus Hollow fiber Dialyzer(K923727), DYNAMIC Hollow Fiber DS-Series, Model: DS-190(K982134).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2002

Dr. Yaw C. Yang
President
Dynamic Technology Corp.
2F, 53 Park Ave. II,
Science-Based Industrial Park
Hsinchu
TAIWAN

Re: K011537
Trade/Device Name: DYNAMIC Hollow Fiber Dialyzer DS-Series, Models Polysulfone 100 HFS (DS-100) and Polysulfone 130 HFS (DS-130)
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: October 4, 2001
Received: October 9, 2001

Dear Dr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Appendix I

2

510(k) Number (if known): K011537

Device Name: DYNAMIC Hollow Fiber Dialyzer DS-Series,

**Model: POLYSULFONE 100 HFS (DS-100),**

**POLYSULFONE 130 HFS (DS-130)**

Indications for Use:

The DYNAMIC Hollow Fiber Dialyzer DS-Series, model: POLYSULFONE 100 HFS(DS-100), POLYSULFONE 130 HFS(DS-130) are indicated for use whenever a patient is in acute or chronic renal failure and hemodialysis is prescribed by a physician. Therefore, use of this device should be only on the direction of a physician who has evaluated all of the aspects of the patient's illness.
This device recommended for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office Device Evaluation (ODE)

Nancy C Brogdon

(Division Sigh-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011537

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)